
**NATIONAL CUSTOMS BROKERS &
FORWARDERS ASSOCIATION OF AMERICA**



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April 4, 2003

Food and Drug Administration
Dockets Management Branch (HFA – 305)
5630 Fishers Lane
Room 1061
Rockville, M.D. 20852

**Re: Comments on Proposed Notices of Rulemaking:
Docket Numbers 02N-0276 and 02N-0278**

Dear Sirs:

The following is submitted by the NCBFAA and on behalf of the organizations set forth in the enclosure hereto, in connection with the Notices of Proposed Rulemaking, ("NPRM") published in the Federal Register of February 3, 2003, (68 F.R. 5378) relating to proposed amendments to 21 C.F.R. Part 1, implementing the relevant provisions of the P.L. 107-188, the "Public Health Security and Bioterrorism Preparedness and Response Act of 2002" (hereinafter referred to as the "Bioterrorism Act" or the "Act").

The NCBFAA is a national organization with regular membership consisting of licensed customs brokers, international freight forwarders, non-vessel operating common carriers, and international air cargo agents.

As set forth in the notice, the FDA believes the proposals will protect U.S. consumers from food imports that may be adulterated or pose other health risks. The proposed rules will amend the Food and Drug Administration ("FDA") regulations to require the prior registration of all domestic and foreign facilities that process food products and the submission of a prior notice of an imported food shipment to FDA by noon of the calendar day before the day of arrival.

02N-0278

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The stated purposes of these proposals is to improve the security of the U.S. food supply

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by enhancing the FDA's ability to inspect imported food upon arrival in the U.S., as well as FDA's ability to deter, prepare for, and respond effectively to bioterrorism and other public health emergencies that might result from importations of food products. Additionally, FDA believes that the proposed regulations would facilitate product tracking for containment, should an outbreak or a bioterrorism event occur and assist the FDA in determining the source and cause of problems.

Because the rules set forth in the two dockets are inter-related, the following comments relate to both dockets.

Comments

At the outset, we wish to express wholehearted support for the intended aim of the proposed regulations - - the protection of the American public. However, as currently set forth in the NPRM, we do not believe that the proposals represent the most appropriate solutions for achieving the purposes of the Bioterrorism Act. As a practical matter, in many instances, the proposed rules are unrealistic, unduly burdensome, and will unnecessarily interdict the normal flow of trade in food products. Its unintended effect will be to impose impossible burdens on U.S. importers, as well as entities involved in the transportation and importation of these products. Therefore, as detailed below, we must object to the implementation of the proposed regulations.

1. The Time For Submission Of Prior Notice Disregards Various Factors That Will Effect The Flow of Trade.

Proposed regulation §1.286 provides that notice "must be submitted by noon of the calendar day before the day the article of food will arrive at the border crossing in the port of entry;" with the further requirement that any amendments to the notice must be received at least three hours before arrival. The authority cited for this regulation, section 801(m) of the Act, states that the deadline for prior notice "shall be no less than the minimum amount of time necessary for the [FDA] to receive, review, and appropriately respond to such notification." Yet, the "Background" section contains no adequate explanation or reasons why this unduly long prior

notice period is required, particularly for shipments coming from Canada and Mexico.¹

The NPRM also fails to adequately address section 801(m)(2)(A) of the Act, which provides that the FDA consider “other factors” when deciding the deadline for prior notice, specifically: its effect on commerce; the locations of various ports; various modes of transportation; types of food; and any other consideration. In this regard, the NPRM appears to take no account of the myriad of business and transportation factors, such as motor and rail transit times from contiguous countries, that effect the period between when food products are ready to be shipped to the United States and their actual arrival at the border. It also overlooks perishable food products that are loaded aboard the transportation conveyance at the farm, as well as the possible effect of local weather conditions on fresh produce, that can adversely impact transit time. Further, the time frame is also impractical with regard to the shipment of baked goods, fresh fish and seafood; most often, the exact variety and quantity of such products cannot be determined by noon of the prior day. At the least, if the FDA does not address these concerns and revise the proposed regulations, they will drastically effect on food shipments arriving from contiguous countries and from the Caribbean.²

Ocean vessels rarely arrive at the time originally scheduled. However, the person required to file the prior notice does not have access to that information and, most often, only becomes aware of the vessel’s arrival via notification from the carrier. Requiring estimated date and time of arrival reporting and/or amendments where the shipment will be delayed by three hours or arrive one hour earlier necessitates “24x7x365” operation by importers or their agents (*i.e.*, Customs brokers), as well as other service providers in the supply chain, particularly so on the northern U.S. Border. The strict time periods provided for notice will also eliminate the current method by which international overnight air carriers presently conduct business. Typically, cargo on international flights is loaded and detailed well after noon of the calendar day prior to its arrival at the destination port. As such, the exhaustive details required on the prior

¹ The fact that FDA does not have employees at every port of entry is not justification for imposing this requirement on shipments from Mexico and Canada.

² For example, if coffee is sent by vessel from Honduras on a Friday, the shipper does not receive his copy of the bill of lading until Monday, which will be after the vessel has arrived in Miami; this will mean that every such shipment will be refused by FDA because of an incomplete prior notice.

notice, as set forth in the proposed regulation are not known by the time provided for submission. Even assuming that compliance is possible, it will only happen at great expense to both the shippers and the carriers, who will have to completely revise their current shipping schedules.

Even in situations where the transit time is longer, cargo scheduled for a particular trip may not be ready in time for shipment. Since cargo space is at a premium, carriers need the ability to substitute other cargo. If this occurs after noon of the calendar day prior to importation, the regulations preclude this because proposed regulation section §1.289 only allows amendments concerning the last two digits of the FDA product code and other product information that provides the specific identity of the article, such as the brand name or common trade name. A prior notice may not be amended to completely change the identity of the article. Instead, the filer must cancel the initial prior notice and submit a new one. In these instances, to require prior notice to be filed by noon of the calendar day prior to importation is impractical and will have the effect of delaying cargo either at the port of entry or at a secure facility, because valid commercial considerations make it impossible for the entry filer to timely file the prior notice.

Equally problematic is the impact of the different time zones involved in international trade. For any given shipment, with the possibility of a dozen or more time zone differences in play, the reporting requirement is silent as to which time zone (*i.e.*, place of shipment or place of arrival) will govern. If the time at the port of arrival governs, an importer can be subject to the assessment of penalties and delays in deliveries, by reason of not timely transmitting the information. This, in turn, can increase both the shipper's and the importer's inventory costs, with resultant higher prices for consumers. The regulation should specify which time zone that applies.

In the present economy, where profit margins have already decreased considerably, the cost of complying with regulations is a primary concern by industry. For example, freight forwarders, regardless of the size of their operation, are "eating costs" in order to update their software and/or facilities to conform to the manifest reporting requirements already in place

pursuant to Customs regulations. To require the trade industry to invest yet another round of software and other technical upgrades in order to adhere to additional and differing reporting requirements from the FDA, creates an unreasonable financial burden on the industry.

As noted below, to avoid duplication of effort, it is essential the FDA cooperate with the Bureau of Customs and Border Protection ("Customs") by sharing the arrival data submitted via the Automated Manifest System ("AMS") or Border Cargo Selectivity ("BCS") systems. Otherwise, it is likely that the data given to FDA will not be consistent with that given to Customs.

2. The NPRM Will Unnecessarily Create A New Electronic Interface For Importers, With New Requirements.

Although the NPRM states that the FDA has consulted with Customs prior to promulgation of this notice, the Commissioner of Customs stated publicly that he was unaware of the NPRM, or its requirements. It is essential that FDA and Customs work together with each other and the trade to arrive at a single system, with realistic requirements.

Customs currently has issued requirements for the filing of a cargo declaration twenty-four hours prior to *lading* on board an ocean vessel. Moreover, pursuant to Section 353 of the Trade Act of 2002, and in conjunction with The Treasury Advisory Committee on Commercial Operations of the United States Customs Service ("COAC"), Customs is studying the requirements for other modes of transportation. Customs is also developing its Automated Commercial Environment (ACE), which will replace all current systems.³

Through the Automated Commercial System ("ACS") importers and Customs brokers electronically provide import data to Customs for FDA's Operational and Administrative System for Import Support ("OASIS"). Section 1.286 would, in essence, require that importers provide a

³ Use of the International Trade Data System ("ITDS") should be seriously considered as the means to obtain the data; that is the only way to eliminate confusion and insure the highest compliance percentages, while, at the same time, affording the least disruption to trade.

second "advance entry" over the Internet, to FDA. This will cost the importer both time and money, will not operate as contemplated, and, given the Customs requirements, is unnecessary.

The proposal suggests that data transmission could be accomplished with a simple computer over 56K line. This is a flawed assumption. In view of the high volume of advance notices which must be filed each day, transmitting over a website portal is impractical, especially for high volume importers. Based on experience with Customs transmissions, this large amount of data would require high-speed batch data processing over dedicated lines.

The notice also makes unrealistic assumptions regarding the current state of computer capabilities in the food trade - - many suppliers simply do not have the equipment and/or expertise to prepare and transmit the data required under section 1.288. Most important, use of an Internet website leaves the system open to "hackers" and others that intend to do harm to our food supply.

Further, this also means that much of the same data will have to be input twice: once for Customs over ABI and again for FDA over the Internet. This unnecessary redundancy increases the risk of transmitting incorrect data through clerical error.

3. The Proposed Regulations Will Require New ABI Software.

Proposed rule 1.288 requires that the Customs entry number as well as a detailed line item data be presented on the prior notice. Today, under the systems in use by every Customs filer, the entry number is generated at the time the data is input into ABI. Meeting the FDA time requirement will involve a major redesign of the systems and will lead to duplications and errors. Moreover, given that ACE will shortly replace ABI, such expenditures cannot be justified. This is another reason supporting the use of a single transmission to Customs containing the information needed by FDA.

4. Detaining Cargo At Arrival Terminals Will Congest The Ports.

If an import does not meet all prior notice criteria, section 1.278 requires that the cargo be held at the arrival port or at an “approved storage facility,” other than the importer’s premises.⁴ Currently, pending FDA review, examination, sampling, and eventual disposition, an importer is already obligated under its import bond, to provide for the transport to and holding intact at its facility, of all FDA regulated goods. This procedure works well and should not be discontinued, merely because of a defect in the prior notice.

5. Registration of All Facilities With FDA Is Duplicative.

Many of the facilities that will become subject to registration under proposed section 1.225 are already registered with the FDA and/or other federal regulatory agencies. For example all bonded warehouses have been assigned facility numbers and/or Facilities Information and Resource Management System (“FIRMS”) code. To facilitate efficiency, minimize duplicate reporting of information, FDA should, wherever possible, use the Customs Service FIRMS code, reported on Customs documents and in Customs entry data transmissions, as the primary location identifier for imported food items being held in a “secure facility” in accordance with proposed §1.241(e). Further, to minimize confusion, especially about which of one facility’s multiple registration numbers apply to what types of activities, we strongly recommend that FDA include, on its food facility registration form 3537 or electronic equivalent, optional fields for:

(1) Type of other facility registration number, with checkable options including the above types of registration codes, as well as an option for an “other” type of code, and

(2) The appropriate registration number for each option that is checked.⁵

⁴ This presents an insurmountable problem in the case of merchandise that is intended for “immediate exportation” or “transportation and exportation:” in these situations, the obligations default to the carrier, who does not have the requisite knowledge either to file an adequate prior notice and/or correct a defect.

⁵ The FDA food facility registration number should be cross-linked in the FDA database with each other type of facility registration number (if any) that also applies to that facility.

6. The Proposed Rules Use Terms and Definitions That Are Incompatible With Their Traditional Meaning In Customs And International Trade

As set out in proposed section 1.227(c)(9), “*Port of Entry*” is defined as “the water, air, or land port at which the article of food is imported or offered for import into the United States, i.e., the port where food first arrives in the United States.” This definition is inconsistent with that used by Customs to denote the port where a Customs entry is lodged, together with, when applicable, FDA data via ABI to OASIS.⁶ Use of this definition will lead to confusion and likely result in the incorrect completion of the prior notice. The term should be changed to “Port of First Arrival,” and the definition of “Port of Entry” should be modified to make it compatible with the term as it appears in 19 C.F.R. §101.1, and as it is traditionally understood by the import trade.⁷

The NPRM does not define “*Submitter*,” although it uses that term frequently throughout the background discussion in the NPRM. At page 5433 of the notice, it states, “*FDA notes that the submitter is the entity responsible for ensuring the adequacy and accuracy of the prior notice.*” For the reasons noted below, a customs broker often acts as the agent of the importer but should not be considered liable for incorrect or inaccurate information.

Proposed §1.277(c)(2), FDA adds a new definition for the “*origin*” of imported goods as the “country from which the article of food was shipped defined as loaded aboard the conveyance that brings it into the United States.” This definition fails to take into account what frequently occurs in the international transportation industry. Both ocean and air carriers routinely use “feeder” vessels/aircraft to move cargo from the country of origin to a “gateway,” for transfer to a larger vessel or aircraft, that will transport the cargo to its final destination. The

⁶ Specifically, 19 C.F.R. 101.1 defines “Port of Entry” as “any place designated by Executive Order of the President, by order of the Secretary of the Treasury, or by Act of Congress, at which a Customs officer is authorized to accept entries of merchandise to collect duties, and to enforce the various provisions of the Customs and navigation laws.”

⁷ Further, as noted above, requiring that the importation be held at the port of first arrival, will seriously interdict the ability of carriers to arrange the in-bond transportation of merchandise, destined for entry at inland ports and will place importers of goods intended to move in-bond in the position where they may have to arrange storage at ports where they do not do business and do not employ a customs broker.

importer/submitter does not necessarily know when and where this may occur. Moreover, ocean vessels frequently discharge containers destined for the U.S. in Canada, where they are transferred to a motor carrier for transport to the U.S.⁸

The proposed definition requires that the submitter reflect the "origin" of the goods as the place it was put on the conveyance to the U.S. We fail to understand what possible use this information can be to the FDA and/or how it will impact on determining if the product has been adulterated. Certainly, the rule will confuse importers and require them to (needlessly) attempt to obtain the cargo routing from the master carriers. We believe that the requirement should be changed to reflect the country where the product originated and or was last stored.

Finally, proposed section 1.286(a) requires that prior notice be submitted by noon of the day before the article of food will arrive at the "*border crossing in the port of entry.*" That term may be clear when used with regard to goods imported through a port on the Mexican and Canadian border, however, with regard to ocean vessels, the Customs' definition of "date of importation" is defined in 19 C.F.R. §101.1 as "the date on which the vessel arrives within the limits of a port on the United States with the intent then and there to unlade." That term has a clear and definite meaning. Unless FDA intends that a different meaning should apply, the regulations should adopt the Customs definition.

7. The Prior Notice Information Required Is Unduly Burdensome

The FDA notes that over 4.7 million entry lines of food were entered during the 2001 fiscal year. FDA now proposes to increase this already overwhelming amount of data by requiring the reporting of more product code breakouts than ever before. Showing of brand name and lot information for canned goods, requiring grower data for produce, and demanding size breakout for seafood, translates into a vast number of additional lines of reporting and creates an unreasonable burden on the importer. We also question whether FDA has the resources to assimilate and react to this increase in data.

⁸ In other instances, a shipment may contain goods with a country or origin of Belgium, that was placed in an ocean container and tendered to the carrier in Brussels; it may then be transported by motor or rail carrier to Rotterdam where it is laden on board an ocean vessel that discharged them in Montreal, from where it is then taken by motor or

FDA is also of the belief that information about a sale is always known at time an order for merchandise is placed. Many transactions are confirmed for a quantity that is to be shipped over a period of time. With fresh produce, it is not uncommon for substitution to be made in the growing fields, during picking process. (For example, an importer may order 40 crates of green lettuce, but the supplier ships 20 crates of red and 20 crates of green.) In some industries, such as seafood, quantities are always subject to change, based upon the day's catch.

Under the proposed regulations, any change in product breakouts or different line numbers would require that a new prior notice process, as well as new customs entry, must be transmitted. This is an inordinate burden upon submitters and entry filers. It will certainly lead to delays in the export of shipments.

Further, in view of the increased number of entry lines proposed, it is impractical to limit the number of amendments to one, (Section 1.290(b)) and require that they be made not later than two hours prior to arrival of goods in the U.S. In light of the volume and variety of data FDA seeks, and the small window of opportunity to obtain and present such data, it is an unrealistic limitation. The proposed regulations must allow for the correction of routine clerical error and/or registration information without limitation, so long as it is received in time for the FDA to react to the new information.

Of equal importance is the fact that the regulations do not require the transmission by FDA of an acknowledgement of a prior notice and/or the fact that it is complete - - the importer will only determine this after arrival, when the cargo is accepted or refused by FDA. To avoid substantial economic harm to importers and the industry at large, this oversight should be corrected.

8. The Responsibilities and Liabilities Of An “Agent” Should Specifically Exclude Licensed Customs Brokers.

The term “U.S. Agent,” as described in proposed §1.227(c)(12) clearly includes customs brokers as parties authorized to submit prior notice. However, the proposals also extend liability for the accuracy of the information submitted in the prior notice, to parties that did not provide the information.

Customs brokers will very likely be called upon to serve as the U.S. agent of the importer under the proposed rule, in that this authority already exists under the Customs Regulations. Pursuant to 19 CFR 141.36, a customs broker is required to obtain a power of attorney to conduct “customs business” and accept service of process, on behalf of a nonresident principal. However, as an agent of the importer, Customs recognizes that the broker is not responsible for the accuracy of the invoice information upon which it relies, in preparing the entry.

Contrary to the above, proposed section 1.278 appears to create liability on the part of the customs broker for the accuracy and timeliness of submissions by non-resident principals. Only the entity supplying the data or a party-in-interest in the transaction should be held liable for the accuracy of the information submitted. In order to permit the continuation of importations by foreign importers, particularly on the Northern U.S. border, FDA must revise the rule to reflect that the customs brokers is merely an agent for the *filing* of information *submitted* by importers, and is not responsible for either the adequacy or accuracy of the data submitted, other than to exercise reasonable care to present the information provided by its client in correct form.

9. Limiting Authorized Parties Submitting Prior Notice To U.S. Agents Is Discriminatory.

While, the proposed regulations do not specifically require foreign facilities to designate a U.S. agent, section 1.225(c) implies that all foreign facilities must have U.S. agents, designated as “agent in charge”. Section 1.232(f) requires that the foreign facility list U.S. contact

information. Under proposed section 1.285(a), the purchaser or importer residing in the U.S. is the party responsible for submitting notice. These proposed regulations fail to take into account the fact that certain types of products, such as coffee, is sold in transit or after release by FDA and Customs. Therefore, the actual consignee information is simply not available at the time the prior notice must be submitted. This could result in a "refusal" by FDA simply because the prior notice information is incomplete. FDA must allow for the foreign shipper to appear as consignee on the prior notice.

10. The Requirements of the NPRM Will Cause Economic Harm To The Importer and Carrier Without A Commensurate Increase In Security.

There are many instances where the geographic distance and subsequent transit time between the foreign port of lading and the U.S. port of discharge is minimal.⁹ If the proposed regulations are implemented as presently drafted, they would impose significant additional costs on the trade industry. Carriers would effectively be barred from loading last minute cargo, resulting in significantly lower revenue. It will also interdict the importers ability to employ a "just in time" inventory system and will increase storage costs.

Exporters would have to deliver merchandise to the carrier sooner than previously required, resulting in increased internal and inventory costs, because additional personnel would be necessary in order to process the advance cargo declarations. Containers delivered to a carrier without sufficient time to comply with the new prior notice requirements would remain on the dock or terminal. This would only serve to allow additional time for our enemies to insert a biological/chemical weapon either directly on the food product or inside the container housing the food.

⁹ Such is the case with shipments between Vancouver, Canada and Bellingham, Everett, Seattle and Tacoma.

11. The List Of Facilities Subject To Registration Will Not Achieve The FDA's Desired Goal Of Product Tracking

The number of facilities potentially subject to registration under proposed §1.225(a) is reflected in Tables 1 through 6 of the NPRM. However, the tables take into account only the types of facilities that are now regarded as being "food storage or handling" locations and overlook many other facilities that a literal reading of the provision, would have to be registered. These facilities include, but are not limited to:

- (a) Rail yards – where many types of shipments, including containerized (whether or not on rail cars at the time), boxcar (both dry carton and refrigerated/frozen), hopper car (typically grain), and bulk liquid (*e.g.*, milk) may be held for extended periods in the course of their through transit;
- (b) Container yards – at marine terminals, off-dock holding yards, truck terminals, rail terminals, etc.;
- (c) LTL truck terminals – where cargo is staged, consolidated, loaded, re-handled, and held for on forwarding, pick-up, or delivery;
- (d) FTL truck terminals – including relay points and "drop lots" where previously loaded trailers are staged or held for pick-up or for exchange to a new power unit;
- (e) Customs bonded Container Freight Stations (CFS facilities) where containerized cargo is often held for Customs clearance (and/or other agency release), and/or trans-loaded from international to domestic transportation equipment;
- (f) Air cargo handling agents; and

- (g) Air, ocean, and truck break-bulk terminals.

Because a single domestic U.S. transportation company, regardless of their size, may have literally dozens or hundreds of such locations, the separate registration of each of these as an individual facility, through which imported food products might occasionally pass, will be a huge and unreasonable burden on many such firms.

We recommend that the FDA only require registration of facilities which are generally or regularly used for the storage and handling of food products. We accordingly suggest that proposed §1.226 be amended by adding the following exemption:

- (g) Transportation facilities at which a shipment of food may be temporarily stored during the course of its transportation. This would include temporary storage at marine, truck, rail, or air carrier terminals, container yards, container freight stations, and similar types of locations but does not include a transportation facility that is used for the storage of food, other than in the ordinary course of transportation or pursuant to §1.241(e) of this part.

12. Registration Of Facilities Under The Proposed Regulations Must Be Verifiable.

Verification of the registration of a facility cannot be verified in that proposed rule 1.243(a) makes the information exempt from public disclosure. Therefore, importers and other “submitters” of the prior notice have no way of verifying if a packer, shipper, warehouse, etc., is properly registered. This could lead to refusal or delay of the shipment by the FDA, for reasons beyond the submitter’s control. In addition, NVOCCs, motor freight carriers with less-than-truckload shipments, and carriers of consolidated shipments, would also encounter delays if they have to segregate a refused food shipment from other cargo.

We believe it unreasonable for submitters not to be able to confirm that a facility is registered until after the cargo arrives. By that time, the importer runs the risk of refusal, possible demurrage or other storage costs, and/or “General Order” charges. It should be incumbent on FDA to timely reject a prior notice that contains an erroneous facility registration number.

13. The Regulations Place An Unreasonable Burden on Carriers.

For imported food products that will merely be transiting the United States in-bond, section 1.286(b) provides that the arriving or in-bond carrier may submit the prior notice. Simply stated, the carriers do not have access to this information or the expertise to prepare and submit the prior notice. It will expose them to the assessment of sanctions for possible submission of a false notice and/or liability to the consignee if the shipment is detained. We suggest that this provision be deleted and "in transit" merchandise be exempted from the rule.

14. The NPRM does not comply with the requirements of the Regulatory Flexibility Act and E.O. 12866.

The Regulatory Flexibility Act (5 U.S.C. 601-612) requires federal agencies to consider the effects of their regulatory actions on small businesses and other small entities and to minimize

undue disproportionate burdens on particular business sectors. Many brokers and other participants in the trade industry located in the U.S. have gross incomes under 18 million dollars per year and are considered "small businesses," as defined in the statute. Contrary to the statement contained in the NPRM, as noted above, the proposed regulations will have a significant impact upon these small entities and subject them to potentially crippling losses of revenue. This, coupled with the increased possibility for monetary penalties for non-compliance, will place the continued existence of the many customs brokers that specialize in food products, at risk.

In addition, we challenge the calculation of one hour as the time required to comply with the proposed regulations. Taking into account the many variables, which includes obtaining an entry number, determining the last port the cargo was shipped from, ascertaining the facility registration numbers, obtaining the names, addresses, etc. of contacts, determining the correct

product code, etc., will take far longer than one hour. If prepared by the importer, we estimate that the time required to acquire and verify the information will take from four to six hours, and possibly longer.

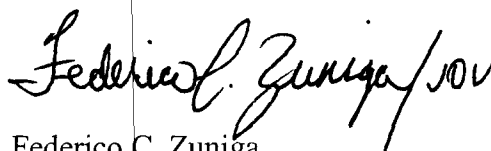
Conclusion

The NCBFAA is anxious to see that regulations are put in place that will help insure against bio-terrorist attacks on our food supplies. However, it appears that the proposed regulations go too far in trying to reach that goal and will have the effect of interdicting the smooth flow of legitimate commerce and economically disadvantage importers, customs brokers, transportation companies and various other entities involved in the supply chain. Further, while security can be measurably enhanced through the transmission of advance import shipment data, the FDA should not strike out to achieve this.

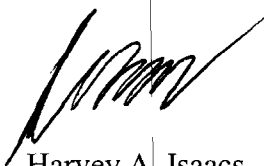
This is certainly not the time for federal agencies to fight "turf wars," at the expense of the public. Rather, FDA should partner with Customs in an effort to find one system that will satisfy the needs of both agencies, at minimum cost to the public. To that end, we believe the NPRMs should be withdrawn, pending substantive discussions between FDA and Customs.

We thank you for the opportunity to submit these comments.

Sincerely,



Federico C. Zuniga,
President



Harvey A. Isaacs
General Counsel

/jov
cc: NCBFAA Board of Directors

ENCLOSURE

LIST OF ORGANIZATIONS ENDORSING THE NCBFAA COMMENTS

Baltimore Customs Broker & Forwarders Association

Charleston Brokers and Freight Forwarders Association, Inc.

Customs Brokers ANC

CB&IFFA of Virginia

Columbia River Customs Brokers and Forwarders

Customs Brokers and Foreign Freight Forwarders Association of Chicago

Customs Brokers and Forwarders Association of Northern California

Detroit Customs Brokers & Freight Forwarders Association

International Freight Forwarders and Customs Brokers Association of Charlotte, NC

International Freight Forwarders and Customs House Brokers of Atlanta, GA

International Freight Forwarders and Customs Brokers Association of New Orleans

Laredo Licensed U.S. Customs Brokers Assn., Inc.

Los Angeles Customs Brokers and Freight Forwarders Association

Northern Border Customs Brokers Association, Inc.

Philadelphia Customs Brokers & Forwarders Association

Rio Grande Valley Customs Brokers Association

San Diego Customs Brokers Association

UPS Supply Chain Solutions, Inc.